



MAR 10 2008

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
to a collection of information unless it contains a valid OMB control number.

Approved for use through 01/31/2008. OMB 0651-0031

<p style="text-align: center;"><i>SECOND SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT BY APPLICANT</i> <i>(Use as many sheets as necessary)</i></p>				<i>Complete if Known</i>	
				Application Number	10/725,009
				Filing Date	December 2, 2003
				First Named Inventor	GEALL, Andrew
				Art Unit	1645
				Examiner Name	HINES, Jana A.
Sheet	1	of	1	Attorney Docket Number	1530.0620001/EJH/UWJ

785926v1

Examiner Signature		Date Considered	
-----------------------	--	--------------------	--

***EXAMINER:** Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. **'Applicant's unique citation designation number (optional):** ² See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.



Equivalent of Form PTO/SB/08b (01-08)
 Approved for use through 01/31/2008. OMB 0651-0031
 U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
PAPERWORK REDUCTION ACT OF 1995, NO PERSONS ARE REQUIRED TO RESPOND TO A COLLECTION OF INFORMATION UNLESS IT CONTAINS A VALID OMB CONTROL NUMBER.

Substitute for form 1449/PTO				<i>Complete if Known</i>	
SECOND SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(Use as many sheets as necessary)</i>				Application Number	10/725,009
				Filing Date	December 2, 2003
				First Named Inventor	GEALL, Andrew
				Art Unit	1645
				Examiner Name	HINES, Jana A.
Sheet	1	of	3	Attorney Docket Number	1530.0620001/EJH/UWJ

NON PATENT LITERATURE DOCUMENTS				
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published		
	NPL-1	BAUMGARTNER, I., et al., "Constitutive Expression of phVEGF ₁₆₅ After Intramuscular Gene Transfer Promotes Collateral Vessel Development in Patients With Critical Limb Ischemia," <i>Circulation</i> 97:1114-1123, Lippincott, Williams, & Wilkins (1998)		T ²
	NPL-2	CHEN, Z-Y., et al., "Linear DNAs Concatemerize <i>in Vivo</i> and Result in Sustained Transgene Expression in Mouse Liver," <i>Mol. Ther.</i> 3:403-410, Academic Press (March 2001)		
	NPL-3	CHENG, S.H., and Scheule, R.K., "Airway delivery of cationic lipid: DNA complexes for cystic fibrosis," <i>Adv. Drug Deliv. Rev.</i> 30:173-184, Elsevier Science B.V. (1998)		
	NPL-4	CHERNG, J.-Y., et al., "Effect of DNA topology on the transfection efficiency of poly((2-dimethylamino)ethyl methacrylate)-plasmid complexes," <i>J. Control. Release</i> 60:343-353, Elsevier Science B.V. (1999)		
	NPL-5	DALESANDRO, J., et al., "Gene Therapy for Donor Hearts: Ex Vivo Liposome-Mediated Transfection," <i>J. Thorac. Cardiovasc. Surg.</i> 111:416-422, Mosby-Year Book, Inc. (1996)		
	NPL-6	DANKO, I., et al., "Dystrophin expression improves myofiber survival in <i>mdx</i> muscle following intramuscular plasmid DNA injection," <i>Hum. Mol. Genet.</i> 2:2055-2061, Oxford University Press (1993)		
	NPL-7	DARQUET, A-M., et al., "A new DNA vehicle for nonviral gene delivery: supercoiled minicircle," <i>Gene Ther.</i> 4:1341-1349, Nature Publishing Group (1997)		
	NPL-8	DAVIS, H.L., et al., "Direct gene transfer in skeletal muscle: plasmid DNA-based immunization against the hepatitis B virus surface antigen," <i>Vaccine</i> 12:1503-1509, Butterworth-Heinemann Ltd. (1994)		
	NPL-9	DOW, S.W., et al., "Systemic and Local Interferon γ Gene Delivery to the Lungs for Treatment of Allergen-Induced Airway Hyperresponsiveness in Mice," <i>Hum. Gene Ther.</i> 10:1905-1914, Mary Ann Liebert, Inc. (1999)		
	NPL-10	GRAMZINSKI, R., et al., "Immune Response to a Hepatitis B DNA Vaccine in <i>Aotus</i> Monkeys: A Comparison of Vaccine Formulation, Route, and Method of Administration," <i>Mol. Med.</i> 4:109-118, The Picower Institute Press (1998)		

Examiner Signature		Date Considered
--------------------	--	-----------------

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Applicant's unique citation designation number (optional). ² Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449/PTO				<i>Complete if Known</i>	
SECOND SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(Use as many sheets as necessary)</i>				Application Number	10/725,009
				Filing Date	December 2, 2003
				First Named Inventor	GEALL, Andrew
				Art Unit	1645
				Examiner Name	HINES, Jana A.
Sheet	2	of	3	Attorney Docket Number	1530.0620001/EJH/UWJ

NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	T ²
	NPL-11	HARLAND, R., and Misher, L., "Stability of RNA in developing <i>Xenopus</i> embryos and identification of a destabilizing sequence in TFIIIA messenger RNA," <i>Development</i> 102:837-852, The Company of Biologists Limited (1988)	
	NPL-12	HORTON, H.M., et al., "A gene therapy for cancer using intramuscular injection of plasmid DNA encoding interferon α ," <i>Proc. Natl. Acad. Sci. USA</i> 96:1553-1558, National Academy of Sciences (1999)	
	NPL-13	LEVY, M.Y., et al., "Characterization of plasmid DNA transfer into mouse skeletal muscle: evaluation of uptake mechanism, expression and secretion of gene products into blood," <i>Gene Ther.</i> 3:201-211, Nature Publishing Group (1996)	
	NPL-14	MIR, L.M., et al., "High-efficiency gene transfer into skeletal muscle mediated by electric pulses," <i>Proc. Natl. Acad. Sci. USA</i> 96:4262-4267, National Academy of Sciences (1999)	
	NPL-15	MOFFATT, M., and Cookson, W., "Naked DNA: New shots for allergy?," <i>Nat. Med.</i> 2:515-516, Nature America Inc. (1996)	
	NPL-16	NOVO, F.J., et al., "Gene transfer and expression of human α -galactosidase from mouse muscle in vitro and in vivo," <i>Gene Ther.</i> 4:488-492, Nature Publishing Group (1997)	
	NPL-17	PELLETIER, J., and Sonenberg, N., "Internal initiation of translation of eukaryotic mRNA directed by a sequence derived from poliovirus RNA," <i>Nature</i> 334:320-325, Macmillan Magazines Ltd. (1988)	
	NPL-18	PICCIRILLO, C.A., and Prud'homme, G.J., "Prevention of Experimental Allergic Encephalomyelitis by Intramuscular Gene Transfer with Cytokine-Encoding Plasmid Vectors," <i>Hum. Gene Ther.</i> 10:1915-1922, Mary Ann Liebert, Inc. (1999)	
	NPL-19	PICCIRILLO, C.A., et al., "TGF- β 1 Somatic Gene Therapy Prevents Autoimmune Disease in Nonobese Diabetic Mice," <i>J. Immunol.</i> 161:3950-3956, The American Association of Immunologists (1998)	
	NPL-20	QIN, L., et al., "Gene Transfer for Transplantation - Prolongation of Allograft Survival with Transforming Growth Factor- β 1," <i>Ann. Surg.</i> 220:508-519, J.B. Lippincott Company (1994)	

Examiner Signature		Date Considered	
--------------------	--	-----------------	--

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Applicant's unique citation designation number (optional). ² Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449/PTO				<i>Complete if Known</i>	
SECOND SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(Use as many sheets as necessary)</i>				Application Number	10/725,009
				Filing Date	December 2, 2003
				First Named Inventor	GEALL, Andrew
				Art Unit	1645
				Examiner Name	HINES, Jana A.
Sheet	3	of	3	Attorney Docket Number	1530.0620001/EJH/UWJ

NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume number, publisher, city and/or country where published	T ²
	NPL-21	QIN, Y.-J., <i>et al.</i> , "Gene Suture - A Novel Method for Intramuscular Gene Transfer and its Application in Hypertension Therapy," <i>Life Sci.</i> 65:2193-2203, Elsevier Science Inc. (1999)	
	NPL-22	RAGNO, S., <i>et al.</i> , "Protection of Rats from Adjuvant Arthritis by Immunization with Naked DNA Encoding for Mycobacterial Heat Shock Protein 65," <i>Arthritis Rheum.</i> 40:277-283, American College of Rheumatology (1997)	
	NPL-23	RESTIFO, N.P., <i>et al.</i> , "Enhancing the Recognition of Tumour Associated Antigens," <i>Folia Biologica</i> 40:74-88, Institute of Molecular Genetics (1994)	
	NPL-24	SCHRIJVER, R.S., <i>et al.</i> , "Immunization of cattle with a BHV1 vector vaccine or a DNA vaccine both coding for the G protein of BRSV," <i>Vaccine</i> 15:1908-1916, Elsevier Science Ltd. (1997)	
	NPL-25	TRIPATHY, S.K., <i>et al.</i> , "Long-term expression of erythropoietin in the systemic circulation of mice after intramuscular injection of a plasmid DNA vector," <i>Proc. Natl. Acad. Sci. USA</i> 93:10876-10880, National Academy of Sciences (1996)	
	NPL-26	TSURUMI, Y., <i>et al.</i> , "Direct Intramuscular Gene Transfer of Naked DNA Encoding Vascular Endothelial Growth Factor Augments Collateral Development and Tissue Perfusion," <i>Circulation</i> 94:3281-3290, Lippincott, Williams, & Wilkins (1996)	
	NPL-27	ULMER, J.B., <i>et al.</i> , "Immunization Against Viral Proteins with Naked DNA," <i>Ann. N.Y. Acad. Sci.</i> 772:117-125, New York Academy of Sciences (1995)	
	NPL-28	VAHLSING, H.L., <i>et al.</i> , "Immunization with plasmid DNA using a pneumatic gun," <i>J. Immunol. Methods</i> 175:11-22, Elsevier Science B.V. (1994)	
	NPL-29	YAGI, K., <i>et al.</i> , "Basic Study on Gene Therapy of Human Malignant Glioma by Use of the Cationic Multilamellar Liposome-Entrapped Human Interferon β Gene," <i>Hum. Gene Ther.</i> 10:1975-1982, Mary Ann Liebert, Inc. (1999)	

785928v1

Examiner Signature	Date Considered
--------------------	-----------------

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹Applicant's unique citation designation number (optional). ²Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.